K001300

AUG 3 0 2000

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and Title 21 CFR 807.92

A. Applicant & Submitted By:

D.R. Medical Company
4200 de Rouen suite 200
Montreal, Quebec, Canada
H1V 3T2
Tel: 514-252-5553
Fax: 514-252-4417

Contact Person: Guy Houde, Vice-President

Date Prepared: April 15,2000

B. Device Name:
a. Trade name: D.R.Medical controlled pressure garments
b. Common or usual name: Pressure garments
c. Classification name: Medical Support Stocking, 21 CFR 880.5780

C. Predicate Device:
Medical Z Corporation custom pressure garments, Bio-Concepts pressure garments

D. Device Description:
The main purpose of D.R. Medical pressure garments to provide constant and even pressure on burn scars in order to control and diminish the appearance of hypertrophic scars.
D.R. Medical controlled pressure burn garments are custom- made garments, which act in place of natural skin, replacing the pressure that normal skin provides, controlling the developing skin and helping it grow in a smooth, orderly way. Depending on the degree of burn D.R. Medical manufactures different items of pressure garments.

E. Intended Use
D.R. Medical pressure garments are to be used only by prescription in order to erase or diminish the appearance of hypertrophic scars, which are results of burn accidents

F. Comparison to Predicate Device

	Medical Z	Bio-Concepts	D.R. Medical
Indications for use	Intended for use to treat burn scars(kelloids and hypertrophic scars) and limphedemia	Same	Same
Target population	Burned victims and people suffering limphedemia	Same	Same
Design	Individually designed, accordingly to	Individually designed and ready made	Individually designed

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	patient's needs	pressure garments	
Performance	All burn centers in USA use pressure burn garments, thus recognizing their effectiveness The burn garments are tested on adequate pressure by Harbor View Medical Center in Seatle (Washington)	Same (except we do not have any information on how these garments are tested)	Same Montreal Regional Burn Center (Hotel Dieu) has recognized and approved D.R. Medical pressure garments
Where used	Pressure burn garments used in hospitals and at home	Same	Same
Composition of fabric	PowerNet (fabric does not carry any medications)	Silicon-Tex (silicon impregnated fabric) and Oleeva(does not carry any medications)	PoweNet and Rashell fabrics (do not carry any medications)
Standards met	These garments are prescribed items. Occupational therapists are credited to confirm whether the garments met their standards.	Same	Same

G. Conclusion:

Based on the detailed device description, the intended use of the device, the range of pressure, the characteristics of the fabric and the fact that occupational therapists believe in high performance of pressure garments D.R. Medical Company believes that the subject device demonstrates a substantial equivalence to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2000

Mr. Guy Houde
Vice President
Confection Medicale D.R., Incorporated
4220 De Rouen Street #200
Montreal, Quebec
CANADA

Re: K001300
Trade Name: D.R. Medical Controlled Pressure Garments
Regulatory Class: II
Product Code: DWL
Dated: June 26, 2000
Received: June 30, 2000

Dear Mr. Houde:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _K001300_____

Device Name: _____Controlled Pressure Garments_____

Indications for Use:

Controlled Pressure Garments are intended to be used for hypertrophic scars management.
Controlled pressure garments may also be used for lymphatic diseases such as lymphedema and edema.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurence of CDRH, Office of Device Evaulation (ODE)

(Optional Format 3-10-98)

(Posted July 1, 1998)

Patricia Cuccia

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001300